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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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701 Fifth Avenue Suite 6300
Seattle, WA 98104-7092

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EXAMINER

RAWLINGS, STEPHEN L.

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,866

Applicant(s)

AUSTRUP ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10 is/are rejected.
- 7) ☒ Claim(s) 4-7 is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The election with traverse filed September 9, 2002 in Paper No. 10 is acknowledged and has been entered.
2. Claims 1-21 are pending in the application. Claims 8, 9, and 11-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.
3. Claims 1-7 and 10 are currently under prosecution.

Election/Restrictions

4. Applicant's election with traverse of group I, claims 1-7 and 10, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the inventions of groups I, II and III share the same or a corresponding special technical feature, which define a contribution which each of the claimed invention, as a whole, makes over the prior art. In addition, Applicant has argued that examination of the inventions of groups I, II, and III would not constitute a serious burden.

Applicants' arguments have been carefully considered but not found persuasive. The technical feature commonly shared by the inventions of groups I, II, and III, which Applicants have asserted is a "special technical feature", does not constitute a "special technical feature", since contrary to Applicants' assertion, it does not define a contribution over the prior art. Therefore, as noted in the previous Office action mailed August 7, 2002 (Paper No. 8), the inventions of groups I, II, and III do not share the same or corresponding special technical feature. Contrary to Applicants' assertion, the search required for the examination of the invention of group I is not co-extensive with the search required for the examination of either of the other inventions of groups II and III.

The restriction requirement set forth in the previous Office action is, therefore, deemed proper and made FINAL.

Claim Objections

5. Claims 4-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-7 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are vague and indefinite because claims 1 and 3 recite the limitations "characterized in that [...]". Recitation of these limitations renders the claims vague and indefinite because it cannot be ascertained how the claims require the methods to be characterized by passive processes recited in the body of the claim. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. It is unclear how obtaining a retained cell fraction results in isolating disseminated tumor cells.

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Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rye, et al (*American Journal of Pathology* **150**: 99-106, 1997).

Rye, et al teaches a method for isolating tumor cells from blood, bone marrow, ascitic or pleural fluids, and enzyme-digested tissue biopsies, which comprises filtering a suspension of cells through a 20-micron nylon microfilament filter and obtaining a retained fraction of cells.

12. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,265,229-B1.

US Patent No. 6,265,229-B1 teaches a method for isolating micrometastatic tumor cells from various bodily fluids, including blood, bone marrow, and effusions,

which comprises filtering a suspension of cells through a porous membrane having preferably 20 micron pores and obtaining a retained fraction of cells.

Conclusion

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. Each reference teaches methods for isolating or separating cells that involve the use of porous membranes or mesh.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
November 15, 2002

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